AmeriHealth Caritas

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March 1, 2016

United States Senate
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

RE: Health Care and Patient Community Response to Sovaldi and Harvoni Situation

Senators Grassley and Wyden:

With more than 30 years of experience, AmeriHealth Caritas is a mission-driven organization and one of the nation's leaders in health care solutions for those most in need. Headquartered in Philadelphia and operating in 16 states and the District of Columbia, we serve more than 6.9 million Medicaid, Medicare and CHIP members through our integrated managed care products, pharmaceutical benefit management and specialty pharmacy services, behavioral health services and other administrative services.

Given our role in the health care community, we see the evolving, high-cost and specialty drug market as an important component to the future care management of our members. We appreciate your efforts in wanting to understand the issue and its impact on stakeholders, using the Sovaldi scenario as a baseline to discuss impacts and how we can address such situations in the future. In response to your January 21, 2016 letter to the Health Care and Patient Community, we respectfully submit comments on the effects of new breakthrough, single source innovator drugs and their impact to the marketplace and care management programs, and address considerations for the future.

Effects of Breakthrough Medications: Impact on the Marketplace

AmeriHealth Caritas understands the role that new, high-cost specialty drugs can and will play in the care of our members. It is our goal to make new drugs available for those members who will benefit from these breakthrough treatments. However, as noted in your letter, the Sovaldi pricing situation gave a jolt to the healthcare industry and forcing us to evaluate our preparedness in this changing landscape.

As a company, we become aware of potential drugs coming onto the market by closely monitoring drug pipelines. While mindful of these innovative new therapies, we cannot assess their true financial impact as their cost and proposed treatment timeline are not revealed until they are formally released on the market. Additionally, while we receive some data as part of clinical trials,

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the thousands of people treated during the trial increases to millions when made available to the public, impacting financial forecasting as well. The subsequent impact due to the scenario above has the following implications to the Medicaid marketplace:

1. **Cost:** Without knowing the cost, it is difficult for states to factor into the rate setting process the financial impact incurred by Medicaid Managed Care Organizations (MCOs) in providing these drug treatments to members. The risk in providing these medications lies with MCOs, who may not receive additional funds from states to adjust for a new course of treatment. As a Medicaid MCO, there is limited ability to assess cost sharing to members, making it difficult to find more funds, other than to petition the state.

   In recent years, the introduction of high-cost specialty drugs like Sovaldi and Harvoni have occurred after rate negotiations, drug formulary composition and/or state budget process is completed. The impact then becomes an issue of the state having to find the funding necessary to cover the cost of this new treatment, when many of these states are already facing budget shortfalls.

2. **Clinical Evaluation:** As these drugs come on to the market, many states ask MCOs to cover these drugs in a short window of time upon introduction. For instance, one state asks that MCOs cover these drugs 10 days after coming onto the market. The consequence is that MCOs do not have the necessary time to evaluate evidence-based clinical guidelines for coverage, leading to higher than necessary costs to states when these drugs are first made available. When this takes place, ultimately you are taking the "managing of care" out of the equation for a short period of time.

3. **Trending:** Each year, actuaries review state Medicaid budgets and are asked to evaluate the impact of drug treatments on the Medicaid population base. Given the sporadic timing of these particular drugs coming onto the market, trends are not always capable of being developed properly. In the case of Sovaldi, state Medicaid agencies were not able to accurately predict the budgetary impact associated with the cost of the drug because of its unique impact on the Hepatitis C population and evolving clinical guidelines for prescribing the medication. With the Sovaldi situation we saw a "warehousing" effect, a situation in which members were told to wait without treatment because much better treatments were coming. This pent-up demand could not be accurately accounted for in trending, impacting state budgets.

   When Harvoni entered as another medication for Hepatitis C patients, the situation was exasperated as the new drug came in with a new price and treatment timeline, again impacting the ability for proper trending to more accurately determine state budgeting requirements, thus enabling MCOs to provide the most appropriate treatment to their Medicaid beneficiaries.

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Effects of Breakthrough Medications: Care Management

The introduction of Sovaldi and Harvoni into the marketplace had a tremendous impact for individuals with Hepatitis C. These breakthrough drugs reduce the duration of treatment for Hepatitis C patients to 12 weeks time and reduce side effects; clinical trials have shown a 90% or higher cure rate for patients taking the new drugs.

This stated, Medicaid systems in many parts of the country have a disproportionate number of Hepatitis C patients, and therefore state Medicaid agencies and Medicaid MCOs are faced with the delicate balancing act of having to provide care to those most vulnerable in our communities without the luxury of unlimited resources. Medicaid MCOs use tools such as care management to help members manage their health care needs and ensure that they benefit from medical breakthroughs such as drugs like Sovaldi and Harvoni.

To ensure MCOs are prudent stewards of state dollars while they effectively treat the Medicaid population, care management is a necessity. With medications such as Sovaldi and Harvoni, not having consistent care management protocols in place has the power to influence overall success rates in the treatment of the Hepatitis C population. Below, we have highlighted care management concerns that can have a positive impact on the use of breakthrough drugs:

1. **Ensuring Adherence to the Drug Regimen:** Once a member meets the evidence-based clinical criteria for Solvadi or Harvoni, they will be contacted by a nurse case manager with the intent to educate and ensure successful completion of the regimen. The nurse case manager supports the member and reinforces the importance of adherence to the drug regimen through ongoing engagement with the member. For these drugs to be effective, patients must adhere to the regimen prescribed for the drug's use, and in some instances a change in lifestyle may be needed so as to not put oneself in a position to revert to the original disease state that led to the drug being administered.

2. **Utilizing Effective Care Management:** As high-cost specialty drugs like Sovaldi and Harvoni become more mainstream in the Medicaid marketplace, state Medicaid agencies are taking different approaches to care management driven by the clinical criteria used to determine the necessity for these drugs. This has become an issue of concern and is something MCOs continue to work through.

   In some parts of the country we are seeing a tendency of the state to determine criteria for usage of a drug being prescribed to certain disease populations, irrespective of care management programs. In other areas, states mandate care management as part of the criteria for the administration of such drugs. For effective, consistent and quality care, we would like to see care management as a requirement for prescription of the medication, especially in states where the care management

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component is deemed optional. Without proper oversight on adherence, the quality of treatment and member health outcomes may be jeopardized.

3. **Including Prior Authorization Notification:** MCOs and states want to make sure those being prescribed drugs, like Sovaldi and Harvoni, are following the proper course of treatment. To help with this, we would like to emphasize the importance of prior authorization notification. When prior authorization does not take place, such as when a state carves out coverage of medications for a disease state, it is difficult for MCOs to know which members are receiving treatment in real time. If a state stipulates that care management is optional, MCOs are unable to engage with members in therapy in a timely manner. Not understanding this can be detrimental to the overall course of treatment from both an adherence and quality standpoint for members. Not understanding all the components being used for to care for a member can dramatically limit the MCOs ability to effectively manage its members' care as well as the use of state health care dollars.

Effects of Breakthrough Medications: Considerations for the Future

AmeriHealth Caritas understands the importance of the new generation of drugs coming onto the market and the potential they have for curing some of today's most detrimental diseases. While the Sovaldi situation establishes a baseline for discussion, our concerns span the entire specialty pharmacy landscape. Medications, such as those to address cholesterol conditions that were approved last year, have the potential to surpass the financial impact of Sovaldi given their price, the population they can impact and duration of care. In reviewing lessons learned from the increasing presence of these medications over the last 24 months, we would like to offer the following as considerations for the future.

1. Clinical Guidelines are becoming increasingly more important in the ability for plans to manage both cost and care for members receiving breakthrough drugs. The uniqueness of these drugs is changing the way the healthcare industry addresses disease management. Until medications are released, we do not know how the professional organizations will adapt the clinical guidelines. Without a transparent process and an unbiased evaluation of evidence, confidence in guideline recommendations is undermined.

2. Patent protections, particularly in this space, impact the care of those populations in most need of these breakthrough medications. Over the last 24 months, anticompetitive pricing strategies were carried out and prolonged due in part to excessive patent protections that favor maintenance of monopoly pricing, and manufacturers' manipulation of patent rights through legal maneuvering, and subtle changes in dosing, packaging and delivery systems designed only to extend brand price protections and exclude generic manufacturers. Financial incentives to raise prices have also manifested themselves as even companies with no research and development capability have

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acquired the rights to "Orphan drugs" and raised prices up to 750% overnight, taking advantage of sick and poor populations who may lose access to needed drug therapies.

Patent laws that unduly extend patent protections for manufacturers needlessly increase costs to State and Federal drug procurement programs such as Medicaid and Medicare, and should be limited in scope and duration.

3. As a Medicaid Managed Care company, many of the states where we operate have "carved–in" pharmaceutical benefits into our contracts. To help address the medication needs of our members, we work with both name brand and generic drugs. The ability to prescribe generic medications works to even out the impact of the sporadic introduction of breakthrough drugs and keeps price per member per month at negotiated rates with states.

   The rise of newer 'biosimilars', immunotherapy and 'precision medicine' drugs portends a move away from generic alternatives, and may have the effect of delaying or eliminating the eventual reduction of brand pricing premiums, unless proactive FDA regulation or legislative relief allows substitution for biosimilars and new classes of drugs. We understand Congress is evaluating options in this area, and we look forward to working with stakeholders to find a solution.

As a Medicaid Managed Care Organization, we want to provide our members with the proper course of treatment to ensure an effective use of these drugs. We want to be a partner in determining the best course of action for all parties involved, and appreciate the opportunity presented by your request of stakeholder input to be part of this dialogue.

If I can provide any additional information, or address any concerns or questions you may have, please do not hesitate to contact me at 215-937-8324 or agelzer@amerihealthcaritas.com.

Sincerely,

Andrea Gelzer, MD, MS, FACP
Corporate Chief Medical Officer
AmeriHealth Caritas